

583-252-0 FWC DIV

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF:

MANFRED ASSMUS ET AL O I P E

EXAMINER: SELLERS

SERIAL NO. 08/813,950

JUN 21 1999

FILED: MARCH 3, 1997

GROUP ART UNIT: 1712

FOR: THERMOPLASTIC COATING AND
BINDING AGENT FOR MEDICINAL
FORMSDECLARATION UNDER 37 C.F.R. §1.132ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

I, Manfred Assmus, declare and state as follows:

1. I am a coinventor of the above-identified application.
2. The following experiments were carried out by me and/or my supervision and control,

EXPERIMENTS

Examples (under 100°C)

Procedure:

Eudragit® RS PO, a copolymer from 65 wt.% methyl methacrylate, 30 wt.% ethylacrylate and 5 wt.% 2-tri-methyl-ammoniumethylmethacrylate chloride, was mixed with 20, 30, 40, 50, 60, 70 and 80 wt.% glycerol-monostearate (GMS) for 30 min. in a blender and subsequently heated in an oven at 60, 65 und 80°C for 1 hour.

Results:

1 = white powder, inhomogeneous

2 = white porous agglomerate, inhomogeneous

3 = white, opaque to homogeneous melt

4 = white, almost clear homogeneous melt

GMS wt. %	60°C	65°C	80°C
20	1	1	2
30	1	1	2
40	1	1	2
50	1	1	2
60	1	1	2
70	1	1	3
80	1	2	4

Conclusion:

None of the melts representative of the prior art was (absolutely) clear and homogeneous, optical clarity not being reached even at 80°C. Temperatures under 100°C thus are not suitable for the purpose of the invention requiring claimed components A) and B) to be miscible in the melt state recognizable by optical clarity of the melt (page 7, line 22, of the specification) so as to obtain a product as claimed.

As one skilled in this art, I consider the results obtained by the practice of the claimed invention to be unobvious and unexpected and of significant and material import.

3. The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false

statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

4. Further, declarant saith not.

Manfred Assmus
Manfred Assmus

99-06-27
Date

I:\atty\SHB\05830252.de